

REMARKS

I. Interview Summary

Applicants thank Examiner Coleman for the courtesy extended to Applicants' representatives in the July 13, 2006, interview. During that interview, the provisional obviousness-type double patenting rejection was discussed. Applicants' representatives pointed out that in view of the definitions of -A—B in this application, and the definitions of R³ and R⁴ in copending application 10/495,494, there is no overlap in the claimed structures. The Examiner indicated that, upon further review of the definitions of these groups in the claims and in the specification, the provisional obviousness-type double patenting rejection was inapplicable and would be withdrawn in the next Office Action.

II. Status of the Claims and Amendments

Claims 1-12 were pending. Applicants have canceled claims 11 and 12 and amended claims 1-8 and 10. Support for the amendments to claims 1-8 and 10 can be found in the original claims, particularly the recitation in claim 1 that the claims are drawn both to the compounds and to the pharmaceutically acceptable salts.

Claims 1-10 are under consideration.

III. Rejection Under 35 U.S.C. § 112, first paragraph

Claim 11 stands rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Office Action, page 2. According to the Office, claim 11 is directed to a pharmaceutical composition for use as an arginine vasopressin V₂ receptor agonist. *Id.* at 3. The Office alleges, however, that the claim

encompasses unpredictable *in vivo* physiological activities related to various disease states, so that there must be sufficient disclosure to enable treatment of those diseases. *Id.* at 3-4.

Applicants traverse this rejection. The Office has not pointed to any reasons or evidence to support its assertion that it would require undue experimentation to practice the methods of treating it alleges are implied by the pharmaceutical composition recited in claim 11. Accordingly, the Office has not met its burden of establishing that there is any basis to question the enablement of claim 11. Further, there is no basis for requiring enabling support for specific methods of treating when the claim recites only a pharmaceutical composition that is an arginine vasopressin V₂ receptor agonist. Applicants respectfully submit that the specification provides ample support that compounds within the scope of claim 11 would function *in vivo* as V₂ receptor agonists because the specification shows that they function as antidiuretics. Nevertheless, Applicants have canceled claim 11 solely to expedite prosecution in this case. They respectfully request the Office to acknowledge that the rejection of record does not apply to the pending claims.

IV. Rejections Under 35 U.S.C. § 112, ¶2

Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Office Action, page 4. Applicants note that claims 11 and 12 have been cancelled, so that any rejections with respect to those claims are now moot.

A. “Derivative”

Claims 1-12 stand rejected because, according to the Office, they “are vague and indefinite in that it is not known what is meant by ‘derivative.’” Office Action, page 4. The Office suggests replacing “derivative” with “compound.” *Id.*

Applicant’s traverse the Office’s position, but have nevertheless amended claim 1 in accordance with the Office’s suggestions in order to expedite prosecution. To clarify that this amendment does not narrow the scope of the pending claims, Applicants have also amended certain dependent claims to explicitly set forth that pharmaceutically acceptable salts are included in those claims.

B. Bracketed Text

The Office notes that the claims include bracketed text that suggests subject matter to be deleted. *Id.* Applicants have removed the brackets in claims 1 and 2, and replaced the language “signs in the formula mean as follows” with “wherein the symbols have the following meanings:”.

C. Duplicative Claims

According to the Office, claims 11 and 12 are substantial duplicates of claim 10 because the statement of intended use is not given patentable weight. *Id.* Applicants have canceled claims 11 and 12, thus rendering the rejection moot.

D. Use of Pharmaceutical

The Office also alleges that claim 11 is indefinite because it “provides for the use of claimed compounds, but the claim does not set forth any steps in determining which

are the diseases capable of being mediated by inhibiting the activity of vasopressin agonist." *Id.* In view of the cancellation of claim 11, this rejection is now moot.

V. Provisional Double Patenting

Claims 1-12 stand provisionally rejected as unpatentable over claims 1-10 of copending application no. 10/495,494. Office Action, page 7. The Office acknowledges that the conflicting claims are not identical, but points to the compounds and compositions of formula (I) of the instant claims when X is -CH=CH- and Y is CH. *Id.*

As discussed in the July 13, 2006, interview, when the definitions of -A—B in this application and the definitions of R³ and R⁴ in copending application 10/495,494 are considered, there is no overlap in the compounds of Formula I of this application and the compounds of Formula I of the copending application. Accordingly, Applicants ask that the Office withdrawn this provisional rejection.

CONCLUSION


In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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